DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

TeleMed Systems, Inc.
Mr. Michael Carrroll
President & CEO
8 Kane Industrial Drive
Hudson, MA 01749

JUL 27 2015

Re: K010412
Trade/Device Name: Flexible Endoscopic Scissors
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCZ
Dated (Date on orig SE ltr): February 1, 2001
Received (Date on orig SE ltr): February 12, 2001

Dear Mr. Carroll,

This letter corrects our substantially equivalent letter of April 2, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010412

Device Name: TeleMed Systems, Inc. Flexible Endoscopic Scissor

Indications for Use:

The TeleMed Systems, Inc. Flexible Endoscopic Scissors are indicated for use for cutting of tissue when used through the working channel of a flexible or rigid endoscope.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

David C. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010412

XI. 510(k) Summary

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K010412

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Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, TeleMed Systems, Inc. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." TeleMed Systems chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name:	**TeleMed Systems Flexible Endoscopic Scissors**
Owner/Operator:	TeleMed Systems, Inc. 8 Kane Industrial Drive Hudson, MA 01749
Manufacturing Site:	TeleMed Systems, Inc. 8 Kane Industrial Drive Hudson, MA 01749
Device Generic Name:	**Flexible Endoscopic Scissors**
Classification:	According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II, Performance Standards (78KOG).
Predicate Devices:	Surgical Scissors marketed by Olympus Corp of America Cuschieri Scissors marketed by Karl Storz Endoskope

Product Description:
The TeleMed Systems Flexible Endoscopic Scissors are reusable, metallic surgical scissors that may be passed through a gastrointestinal endoscope and used to incise tissue.

Indications for Use:
The TeleMed Systems, Inc. Flexible Endoscopic Scissors are indicated for use for cutting of tissue when used through the working channel of a flexible or rigid endoscope.

Safety and Performance:
Substantial equivalence for these devices was based solely on design characteristics; no performance or safety data was included in this premarket notification. The materials, performance specifications and essential design characteristics of the TeleMed Systems device are substantially equivalent to those of the predicate devices.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to predicate devices, the TeleMed Systems, Inc. Flexible Endoscopic Scissors have been shown to be safe and effective for their intended use.